K122063

PHILIPS

August 2, 2013

Philips Healthcare

Islevdalvej 211
2610 Roedovre
Denmark

Anesthesia Care

510 (k) Summary of IntelliSave AX700 Anesthesia System

510(k) Owner: Philips Anesthesia Care
Islevdalvej 211
2610 Rødovre, Denmark

AUG 0 2 2013

Contact Person: Mr. Neil Battiste
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Trade Name: Intellisave AX700 Anesthesia System

Common Name: Anesthesia System

Classification Name: Anesthesia Breathing Machine per 21 CFR §868.5160, product code BSZ.

Predicate Device:

This device is substantially equivalent to the GE Avance Anesthesia Breathing Machine, which was cleared to market on December 11, 2011 via 510(k) K112722.

Device Description:

The Intellisave AX700 suitable for most types of inhalation anesthesia. O_2 and N_2O or O_2 and Air can be administered, and anesthesia vaporizer(s) can be connected to a back bar. The gasses can be supplied from a centralized supply or cylinders. The Intellisave AX700 is a prescriptive device restricted to use by, or on the order of, a physician.

The Intellisave AX700 includes the following:

- An Electronic Gas Mixer (EGM) that allows the operator to choose a fresh gas flow between O_2/N_2O or O_2/Air in the range 0-20 L/min. If N_2O is selected as a carrier gas, the N_2O percentage is limited to 75% (minimum 25% 02). Both a real-time clock and stopwatch are integrated into the electronic gas mixer.
    - An anesthesia ventilator with the following ventilation modes:
    - Volume Controlled Ventilation
    - Pressure Controlled Ventilation
    - Synchronized Intermittent Mandatory Ventilation
    - Pressure Supported Ventilation
    - Pressure Regulated Volume Target
    - Volume Supported Ventilation

- An Integrated Breathing System (IBS) that integrates a bag-in-bottle and patient rebreathing circuit (including an absorber) into the same block. Thus, there are only two hoses (inspiratory and expiratory) from the breathing system to the V-piece. An APL (Adjustable Pressure Limiting) valve integrated into the breathing system allows the operator to choose between manual ventilation or spontaneous respiration.

- An optional multigas module that measures respiration rate, inspired and expired concentrations of N_2O, CO_2 and anesthetic agents. The multigas module has automatic identification of primary and secondary anesthetic agents.

Intended Use:

The Intellisave AX700 Anesthesia System is intended to provide general inhalational anesthesia and ventilation support to neonatal, pediatric and adult patients. The device is intended to provide volume or pressure controlled ventilation.

Summary Of Technological Characteristics:

The Intellisave AX700 Anesthesia Breathing Machine uses has the same technological characteristics as the predicate device. Both are software controlled electromechanical devices designed to deliver inhalation anesthesia during surgery

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Comparison between predicate and proposed device:

The Intellisave AX700 Anesthesia Breathing Machine uses equivalent technology as the GE Avance Anesthesia Breathing Machine (K112722). The following table compares these two devices to confirm substantial equivalence.

	GE Avance	**AX700**	**Comments**
Modes	Volume Control Pressure Control SIMV Pressure Support PCV-VG Cardiac Bypass Mode	Volume Controlled Ventilation Pressure Controlled Ventilation SIMV Pressure Supported Ventilation Volume Supported Ventilation PRVT Heart-Lung Mode	Equivalent
Intended Use	The GE Avance Anesthesia System is intended to provide general inhalation anesthesia and ventilatory support to a wide range of patients (neonatal, pediatric, adult). The device is intended for volume or pressure control ventilation.	The Intellisave AX700 Anesthesia System is intended to provide general inhalational anesthesia and ventilation support to neonatal, pediatric and adult patients. The device is intended to provide volume or pressure controlled ventilation.	Equivalent

Ranges	**GE Avance**	**AX700**	**Comments**
Tidal volume	20 to 1500 mL	20 to 1500 mL	Equivalent
Minute volume:	0 to 99.9 L/min	0.2 to 60.0 L/min	Equivalent
Pressure, inspired:	5 to 60 cmH2O	4 to 67 cmH2O	Equivalent
Pressure limit:	12 to 100 cmH2O	10 to 80 cmH2O	Equivalent
Pressure Support:	Off, 2 to 40 cmH2O	4 to 50 cmH2O	Equivalent

Ranges	**GE Avance**	**AX700**	**Comments**
Respiration Rate:	4 - 100 BPM (VCV, PCV, PCV-VG) 2 to 60 BPM (SIMV, PSV)	4 to 80 BPM	Both within range required for application.
I:E Ratio:	2:1 to 1:8	3:1 to 1:9.9	Equivalent
Flow trigger:	1 to 10 L/min	1 to 10 LPM	Equivalent
Inspiration termination:	5 to 50%	10 to 80% (expiratory triggering)	Both within range required for application.
Inspiratory Pause:	0-60%	0 to 70%	Equivalent
PEEP:	OFF, 4 to 30cmH2O	OFF, 4 to 20 cmH2O	Both within range required for application.
Ventilator gas flow:	Continuous: Max. 80 L/min Peak: 120 L/min	Continuous: Max. 80 L/min Peak: 120 L/min	Equivalent
(fresh gas) Flow compensation:	200 mL/min to 15 L/min	200 mL/min to 20 L/min	Equivalent

Accuracy	**GE Avance**	**AX700**	**Comments**
Tidal volume delivery	> 210 mL: ±7% < 210 mL: ±15mL < 60 mL: ±10 mL	250-1500mL:± 5%, min. 25mL 20-250mL: ±10%, min. 10 mL	Equivalent
Pressure delivery	±10% or ±3 cm H2O	±1 cm H2O	Equivalent
PEEP delivery	±1.5 cm H2O	±1 cm H2O	Equivalent
Tidal volume monitoring	> 210 mL = ±9% < 210 mL = ±18 mL < 60 mL = ±10 mL	Adult sensor: 500- 1500ml = ±10% 200- 500ml = ±50ml Pediatric sensor: 100- 300ml = ±10% <100ml = ±10ml	Equivalent
Pressure monitoring	-20 -100 cmH_2O ±5% or ±2 cm H2O	-20 -100 cmH_2O ±2 cm H2O	Equivalent

Gas Monitor	GE Avance	AX700	Comments
Carbon dioxide	Range:0-15%(0-113mmHg) Accuracy: ±0.2 vol% + 2 % of reading	Range: 0-10% 0-1 %: ±0.1 vol% 1-5 %: ±0.2 vol% 5-7 %: ±0.3 vol% 7-10 %: ±0.5 vol%	Equivalent
Oxygen	Range: 0-100% Accuracy: ±1 vol% + 2 % of reading	Range: 0-100% 0-25 %: ±1 vol% 25-80 %: ±2 vol% 80-100 %: ±3 vol%	Equivalent
Nitrous oxide	Range: 0-100% Accuracy: ±2 vol% + 2 % of reading	Range: 0-100% 0-20 %: ±2 vol% 20-100 %: ±3 vol%	Equivalent
Respiration rate	range: 4 to 60 BPM	Range: 0 to 100 BPM	Equivalent
Halothane	range: 0 to 6% accuracy: ±0.15 vol% + 5 % of reading	range: 0 to 7.5% 0-1 %: ±0.15 vol% 1-5 %: ±0.2 vol%	Maximum vaporizer setting is 5%
Enflurane	range: 0 to 6% accuracy: ±0.15 vol% + 5 % of reading	range: 0 to 7.5% 0-1 %: ±0.15 vol% 1-5 %: ±0.2 vol%	Maximum vaporizer setting is 5%
Isoflurane	range: 0 to 6% accuracy: ±0.15 vol% + 5 % of reading	range: 0 to 7.5% 0-1 %: ±0.15 vol% 1-5 %: ±0.2 vol%	Maximum vaporizer setting is 5%
Sevoflurane	range: 0 to 8% accuracy: ±0.15 vol% + 5 % of reading	range: 0 to 9% 0-1 %: ±0.15 vol% 1-5 %: ±0.2 vol% 5-8 %: ±0.4 vol%	Maximum vaporizer setting is 8%
Desflurane	range: 0 to 20% 0 to 5%: ±0.2 vol %* 5 to 10% ±0.5 vol % 10 to o 20% ±1 vol %*	range: 0 to 20% 0-1 %: ±0.15 vol% 1-5 %: ±0.2 vol% 5-10 %: ±0.4 vol% 10-15 %: ±0.6 vol% 15-18 %: ±1 vol%	Equivalent

In addition to being equivalent to the GE Avance, the gas monitor is exactly the same as that used in the Maquet Flow-i Anesthesia Gas Machine (K102182).

Alarms	GE Avance	AX700	Comments
Low Tidal Volume	OFF, 0 to 1500 mL	N/A	Minute Volume alarms, pressure alarms provide the same information.
High Tidal Volume	20 to 1600 mL, OFF	N/A	Minute Volume alarms, pressure alarms provide the same information.
Low Minute Volume	OFF, 0 to 10 L/min	0.1–79.9 L and OFF	Both within range required for application.
High Minute Volume	0.5 to 30 L/min, OFF	0.1–80.0 L and OFF	Both within range required for application.
Low Inspired oxygen	18 to 99%	18–100%	Equivalent
High Inspired oxygen	19 to 100%, OFF	19–100% and OFF	Equivalent
Low Expired CO2	0.0 to 14.9 %	0.0 to 15.0 %, OFF	Equivalent
High Expired CO2	0.1 to 15 %, OFF	0.0 to 15.0 %, OFF	Equivalent
High Inspired AA	0.1 to 20%, OFF	0.0 to 30.0 %	Equivalent
Low Resp. Rate	0 to 99 BMP, OFF	4 to 80 BPM, OFF	Equivalent
High Resp. Rate	2 to 100, OFF	4 to 80 BPM. OFF	Equivalent
Apnea alarm, information	30 seconds	20 seconds, automatic ventilation	Equivalent
Apnea alarm, high priority	120 seconds	60 seconds, manual and automatic ventilation	Equivalent
Low airway pressure	Below PEEP+4 cm H2O for 20 sec.	Below PEEP+2 cm H2O for 15 sec. (Disconnection alarm)	disconnection alarm
High airway pressure	12 to 100 cmH2O	10–82 cmH2O	
Sustained airway pressure (automatic ventilation)	P_{max}<30 cmH2O:6cmH2O P_{max}30-60 cmH2O: 20% of P_{max} P_{max}>60 cmH2O: 12 cm H2O for 15 seconds (+PEEP-2cmH2O with PEEP on)	PEEP + 5 cmH2O for 15 sec	Equivalent
Alarm silence	120 seconds	120 seconds	Equivalent

Fresh gas	**GE Avance**	**AX700**	**Comments**
Flow range (per gas)	OFF, 100 mL/min-15 L/min	OFF, 100 mL/min to 10 LPM	Both within range required for application.
Total Flow range	OFF, 150 mL/min-15 L/min	OFF, 200 mL/min to 20 LPM	Both within range required for application.
O2 flow accuracy	±5% or ±20 mL/min	±10% or ±50 mL/min	Both within range required for application.
Balance gas flow accuracy	±5% or ±20 mL/min (larger of) Air/N2O	±10% or ±50 mL/min	Both within range required for application.
Total flow accuracy	±10% or ±40 mL/min	±10% or ±50 mL/min	Equivalent
O2 concentration range (Air)	21%, 25 to 100% (Air) 25 to 100% (N2O)	21 to 100% (balance gas Air) 25 to 100% (balance gas N2O)	Equivalent
O2 concentration accuracy	±5% V/V for flows< 1LPM ±2.5%setting;flows>1 LPM	±5% V/V	Equivalent
Compensation	to 20°C and 101.3 kPa	to 20°C and 101.3 kPa	Equivalent
Alternate O2 flow	500 mL/min – 10 L/min	5 L/min – 15 L/min	Both within range required for application.

Electrical Specifications	**GE Avance**	**AX700**	**Comments**
Power input	100-120 Vac, 50/60 Hz	100-120 Vac, 50/60 Hz	Equivalent
Rating	10A@220Vac/15A@120Vac	10A@220Vac/15A@120 Vac	Equivalent
Outlets	3 outlets on back with 2A fuses, and one 3A fuse (120 V), breakers, isolation transformer	3 outlets on back with 3.15A fuse (120 V) and one 1 outlet in front (vaporizer) with 3.15 A fuse. Isolation transformer	Equivalent

Pneumatic Specifications	**GE Avance**	**AX700**	**Comments**
Aux. Fresh gas Outlet	ISO 22 mm OD /15 mm ID	ISO 22 mm OD / 15 mm ID	Equivalent
Gas supply input	35 to 100 psi	58 to 87 psi	Both within range for Operating Room application
Adjustable Pressure Limiting valve	0.8 to 70 cm H2O	Spontaneous, 5 to 75 cmH2O	Equivalent

Environmental Specifications	**GE Avance**	**AX700**	**Comments**
Operation			
Temperature	10° to 40°C	10° to 40°C	Equivalent
Humidity	15 to 95% relative humidity	10 to 90% relative humidity	Equivalent
Altitude	-440 to 3565 m	-100 to 3000 m	Both within range required for application.
Storage			
Temperature	-25° to 60°C/-13° to 140°F	-20° to 60°C	Equivalent
Humidity	10 to 95% RH	10 to 90% relative humidity	Equivalent

Dimensions	**GE Avance**	**AX700**	**Comments**
Height:	136 cm	155 cm	
Width:	76 cm	81 cm	
Depth:	76 cm	79 cm	
Weight:	Appx 135 kg/ 298lb	Appx. 150 kg/331 lb	

Based on the above assessment, we confirm that the Intellisave AX700 Anesthesia Breathing Machine is substantially equivalent to the GE Avance Anesthesia Breathing Machine.

Assessment Of Non-Clinical Performance Data:

The Intellisave AX700 has been thoroughly tested through verification and validation, including software validation, in bench testing under simulated use conditions. Compliance with applicable voluntary standards has also been demonstrated as follows:.

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; with Amendments
- IEC 60601-1-1:2000, Medical electrical equipment -- Part 1-1: Safety requirements for medical electrical systems.
- IEC 60601-1-2:2001,Medical electrical equipment-Part 1-2:Electromagnetic Compatibility-Requirements & Tests w Amendments.
- IEC 60601-1-4; 2000,Medical electrical equipment-Part 1-1-4: Programmable Electrical Medical Systems
- IEC 60601-1-6:2006,Medical electrical equipment-Part 1-1-6: Usability
- IEC 60601-1-8: 2003, Medical electrical equipment - Part 1-8: Alarm systems in medical equipment
- IEC 60601-2-13 Edition 3.1 2009-08, Medical electrical equipment - Part 2-13: Particular requirements for anaesthetic systems.
- ISO 10079-3:1999, Suction equipment powered from a vacuum or pressure source
- ISO 21647:2004, Medical electrical equipment - Particular requirements for respiratory gas monitors.

Assessment Of Non-Clinical Testing:

Clinical performance data was not required to demonstrate conformance to specifications and standards or substantial equivalence.

Conclusion:

The Intellisave AX700 Anesthesia System has been found to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 2, 2013

Philips Anesthesia Care
C/O Mr. Neil Battiste
Islevdalvej 211
Roedovre, Denmark 2610

Re: K122063
Trade/Device Name: Intellisave AX700 Anesthesia System
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas machine for anesthesia or analgesia
Regulatory Class: II
Product Code: BSZ
Dated: July 24, 2013
Received: July 26, 2013

Dear Mr. Battiste:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

FOR

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Intellisave AX700 Anesthesia System

Indications for Use:

The Intellisave AX700 Anesthesia System is intended to provide general inhalational anesthesia and ventilation support to neonatal, pediatric and adult patients. The device is intended to provide volume or pressure controlled ventilation.

Prescription Use __XXX__ (Part 21 CFR 801 Subpart D)

AND/OR

Over the Counter Use ____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Maria Jison
2013.08.02 15:09:44 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Respiratory, Infection Control and
Dental Devices
510(k) Number: K122063